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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,635	04/11/2007	Ira H. Pastan	015280-500100US	4374

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EXAMINER	
DAHLE, CHUN WU	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
10/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,635	PASTAN ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-42 and 50-63* is/are pending in the application.

4a) Of the above claim(s) *58-60* is/are withdrawn from consideration.

5)☒ Claim(s) *17-34, 37-40, 50-55, and 61-63* is/are allowed.

6)☒ Claim(s) *35,36,41,42,56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on August 26, 2010, has been entered.

2. Applicant's amendment to the claims, filed on August 26, 2010, has been entered.

Claims 1-16 and 43-49 have been canceled.
Claims 17-42 and 50-63 are pending.

Claims 58-60 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 4, 2009.

Claims 17-42, 50-57, and 61-63 are currently under consideration as they read on the elected anti-CD22 antibody comprising CDRs of SEQ ID NOs: 7, 11-14, 16, the VL chain of SEQ ID NO:20 and the VH chain of SEQ ID NO:21.

3. This Office Action is in response to Applicant's amendment to the claims and remarks filed on August 26, 2010.

The rejections of record can be found in the previous Office Actions, mailed on October 5, 2009 and March 26, 2010.

4. The search PubMed search results provided by applicant as Exhibits A-G (on August 26, 2010) have been listed on PTO-892. Copies of the search results are not provided.

5. Upon reconsideration, only following rejection has been set forth herein.

6. The incorporation of essential material of the cytolytic fragment PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR in the specification by reference to patents and/or to NPL references {e.g. US Patent 5,602,095, Patent 5,608,039, and US Patent 4,892,827 as well as NPL Mansfield et al. Blood. (1997) 90:2020-2026; Pai et al. PNAS (1991) 88:3358-3362; Kondo et al. JBC (1988) 263:9470-9475; and Debinski et al. Bioconj. Chem. (1994) 5:40-46} is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The attempt to incorporate essential material of the cytolytic fragment of PE toxins into this application by reference to US Patents 5,602,095 and 4,892,827 as well as the non-patent literature references is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, see MPEP 608.01(p),. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Here, the PE40 disclosed in US Patent 5,602,095 is itself incorporates by reference to USSN 07/495,635 and 07/522,182 (e.g. see column 4 of the '095 Patent) and US Patent 4,892,827 does not disclose PE40. The specification discloses that PE4E is found in US Patent 5,512,658 and 4,895,827. However, upon review of these two US Patents, it is noted that PE4E is not disclosed in the Patents.

Applicant is required to incorporate the essential subject matters of the cytolytic fragmentsfrom the US Patents as well as the non-patent literature references disclosed in the instant specification for sequences in the specification and claims. Furthermore, Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

7. Claim 35, 36, 41, 42, 56, and 57 are rejected under **U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

It is apparent that the cytolitic fragments PE35, PE38, PE38KDEL, PE40, PE4E, and PE38QQR are required for making and using the claimed invention. However, Applicant has not provided the sequences of the PE fragments

The amino acid sequence is considered essential subject matter to the instant application and the claimed invention.

Applicant has disclosed that PE40 is taught in Patents 5,602,095 and 4,892,827 as well as the non-patent literature references and PE4E is found in US Patent 5,512,658 and 4,895,827 (e.g. see pages 42-44 of the instant specification), however, these patents failed to disclose the claimed PE fragments. In addition, the relying upon the US Patents for the

disclosure of essential material is not sufficient for a skilled artisan to envision the sequences referred to in the instant claim. Consequently, conception of the invention cannot be achieved until an appropriate written description of the structural and functional properties of the claimed invention has occurred. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Applicant is invited to amend the instant specification to provide the essential subject of the amino acid sequence defining the claimed PE fragments.

Applicant is reminded to provide a Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is further reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the amino acid sequence of PE40.

Applicant's arguments, filed on August 26, 2010, have been fully considered but have not been found persuasive.

Applicant submitted PubMed search results using the claimed PE fragments as search terms and asserts that the PE fragments were recognized in either titles or abstracts of the references in the search results. Applicant further asserts that the PE fragments were disclosed in twenty three US Patents (e.g. see page 13 of the REMARKS filed on August 26, 2010).

Thus, applicant asserts that one of skill in the art would know and recognize the PE fragments as claimed.

This is not found persuasive for reasons stated above. Once again, applicant's

arguments relying upon NPL documents are render moot because the PE fragments being claimed are considered essential material; as such they cannot be incorporated by reference to non-patent publications, especially those NPLs that are not disclosed in the instant specification. With respect to the twenty-three US Patents relied upon by applicant, it is noted that not all of them were disclosed in the instant specification; therefore, there is no nexus between the US Patents relied in applicant's REMARS and the instant specification. In addition, applicant merely listed the US Patents and asserts that the PE fragments were discloses but failed to specifically identify with detailed particularity what specific material it incorporates and clearly indicate where the material is found in the various documents. In addition, as stated above, PE40 is not taught in Patents 5,602,095 and PE4E is not found in US Patents 5,512,658 and 4,895,827 (both Patents were among the twenty-three Patents relied upon by applicant on page 13 of the REMARKS filed on August 26, 2010).

As such applicant's arguments have not been found persuasive.

Once again, an application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

8. Claims 17-34, 37-40, 50-55, and 61-63 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Examiner, Art Unit 1644